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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/974,798

10/12/2001

Ellen M. Heath

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EXAMINER

OLSON, ERIC

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/974,798

Applicant(s)

HEATH ET AL.

Examiner

Eric S. Olson

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-43 and 45-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-43 and 45-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date March 24, 2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted February 21, 2007 wherein claims 21, 30-32, 42, and 45 are amended, claims 1-20 and 44 are cancelled, and new claims 46-71 are introduced. This application was filed October 12, 2001.

Claims 21-43 and 45-71 are pending in this application.

Claims 21-43 and 45-71 as amended are examined on the merits herein.

Applicant's amendment, submitted February 21, 2007, with respect to the rejection of instant claims 21-38, 42-43, and 45 under 35 USC 112, second paragraph for being indefinite, has been fully considered and found to be persuasive to remove the rejection as the amendment addresses all of the issues raised in this rejection. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 21, 2007, with respect to the objection to instant claims 39-41 for depending from non-elected claim 20, has been fully considered and found to be persuasive to remove the objection as the claims have been amended to depend from elected claim 21. Therefore the objection is withdrawn.

Applicant's arguments, submitted February 21, 2007, with respect to the rejection of instant claims 21-38 and 45 under 35 USC 103(a), for being obvious over Heath in view of Wiggins in view of Kuroita et al., has been fully considered and found to be

Art Unit: 1623

persuasive to remove the rejection as none of the cited references teach a method involving a lysing solution buffered with a pH of greater than about 7. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-26, 30-36, 39, 40, 42, 43, 45-53, 57-63, 66, 67, and 69-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Deggerdal et al. (PCT international publication WO96/18731, cited in PTO-1449) Deggerdal et al. discloses a method of isolating a nucleic acid, including RNA, by treating the nucleic acid with detergent and allowing it to bind to a solid support. (p. 5, paragraphs 2-4) The nucleic acid can be isolated from any material containing nucleic acids, including the microorganisms, clinical samples, and environmental samples described in instant claims 23-26 (p. 6, paragraphs 2-3) and can include semi-pure materials as described in instant claim 21. The binding step can be preceded by a lysing step to lyse the biological material. (p. 6, last paragraph) Detergents suitable for use in this invention include any detergent, including non-ionic detergents. (p. 7, last paragraph) Additionally, a source of

Art Unit: 1623

monovalent cations in a concentration of 0.1-1M can be included to increase nucleic acid capture (p. 8, second paragraph) along with a chelating agent such as EDTA. (p. 8, third paragraph) Several examples are provided of lysis solutions in which the monovalent cation is LiCl of up to 0.5M and the solution is buffered at pH 7.5, which is greater than 7. (p. 8, bottom of page) The solid support can be made of any well known solid support material, including non-silica materials such as glass, latex, or a polymeric material, and can be in various physical forms including tubes, plates, or wells. (p. 9, paragraphs 2-3) More than one solid support can be used. (p. 13, second paragraph) After the lysis and binding steps, washing and elution steps can be further performed to wash and isolate the nucleic acid. (p. 12, paragraphs 2-4) Examples are given in which all of the steps (a)-(e) of instant claim 21 are performed, for example, example 1 on p. 19. Binding is described to take place in a micorcentrifuge tube in example 6. (p. 23, lines 20-26) Therefore the procedure described by Deggerdal et al. falls within the instant claims, and Deggerdal et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 38, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, cited in

Art Unit: 1623

PTO-1449) in view of Wiggins. (US patent 5637687, cited in PTO-1449) The disclosure of Deggerdal et al. is discussed above. Deggerdal et al. does not disclose a method in which lithium chloride is included in the lysis solution at a concentration of 4-10M.

Wiggins discloses a method for isolating nucleic acids from biological tissues and cells. (column 3, lines 30-48) In one embodiment, the nucleic acid is isolated from solution by precipitating it from an isopropanol/LiCl solution, or alternately, by adsorbing it from such a solution onto a solid phase support. (column 4, lines 46-67) Lithium chloride is preferably present in a concentration of 2-5M, preferably 4M. (column 12, lines 25-35) In addition to insolubilizing the nucleic acids, the salts also help to solubilize contaminants such as polysaccharides and prevent their precipitation or adsorption along with the nucleic acid. (column 14, lines 10-20)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Deggerdal et al. by adding 4-5M of lithium chloride to the lysis/binding buffer. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Wiggins discloses that these concentrations of lithium chloride lead to increased extraction of nucleic acids from the sample and increased solubilization of contaminants such as polysaccharides. One of ordinary skill in the art would reasonably have expected success because adjusting the concentration of one component of a known mixture is within the ordinary and routine skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Art Unit: 1623

Claims 41 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, cited in PTO-1449) in view of the Calbiochem 2000-2001 reagent catalog. (cited in PTO-892, herein referred to as Calbiochem) The disclosure of Deggerdal et al. is discussed above. Deggerdal et al. does not disclose a method in which the detergent in the lysis buffer is a triton or tween detergent.

Calbiochem discloses various triton (octylphenoxypolyethoxyethanol, p. 541) and tween (polysorbate, polyoxyethylene sorbitan monolaurate, p. 546) nonionic detergents. These detergents are reasonably considered to fall within the scope of nonionic detergents included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use triton or tween detergents in the lysis/binding solution of Deggerdal et al. One of ordinary skill in the art would have been motivated to use these detergents because Deggerdal et al. already discloses that nonionic detergents in general can be used in the lysis buffer. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any detergent can be used successfully, and selecting a particular detergent is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 27-29 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, cited in

Art Unit: 1623

PTO-1449) in view of Heath et al. (PCT international publication WO99/39009, reference included with PTO-892) The disclosure of Deggerdal et al. is discussed above. Deggerdal et al. does not disclose a method in which the solid support is one or more polyesters.

Heath et al. discloses reagents and methods that incorporate a solid support for purifying DNA from samples. (p. 8, lines 8-11) The solid support can be a number of different materials including polyester. (p. 9, lines 12-15) These polyester solid supports are reasonably considered to fall within the scope of solid supports included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use one or more polyesters as the solid supports of Deggerdal et al. One of ordinary skill in the art would have been motivated to use polyesters because Deggerdal et al. already discloses that various solid supports in general can be used to adsorb RNA and Heath et al. specifically discloses that polyester can adsorb nucleic acids. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any solid support can be used successfully, and selecting a particular solid support is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 1623

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-43 and 45-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of copending Application No. 11/589364. (not yet published, Cited in PTO-892, herein referred to as '364) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-85 of '364 cover the entire scope of the claimed invention. In particular, they include the same claimed limitations with the exception that the pH of the lysis solution is either below 4.5 or above 7. Note that while claim 1 of '364 does not mention a detergent, claims 21 and 29-31 do include a detergent in the lysis/binding buffer. Therefore the embodiment of '364 in which the pH is above 7 anticipates the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following rejections of record in the previous office action are maintained:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-25, 27-30, 46-50, and 52-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 189 of co-pending U.S. Application Ser. No. 09/154,830 ('830). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the instant application (claims 21-25, 27-30 and 45) and the '830 co-pending application (claims 1 and 189) are directed to substantially the same subject matter, i.e., in the instant claims, the invention is claimed in terms of a method for purifying undegraded RNA from biological material comprising the steps of: mixing the biological material with an RNA lysing solution, forming a lysate, contacting lysate to an

Art Unit: 1623

immobilized non-silica solid support; or contacting a biological material containing RNA with a solid support pre-treated with an RNA lysing solution, washing the solid support with an RNA wash solution and eluting the bound RNA from solid support, while in the '830 c0-pending application it is claimed in terms of a process for obtaining purified nucleic acids comprising the steps of: contacting a sample containing nucleic acid with a solid support pre-treated with an lysing solution, loading the solid support into a sample processing container, purifying the nucleic acid, isolating the nucleic acid from solid support and collecting the nucleic acid. The specification of '830 discloses the source of the sample containing nucleic acid claimed in claims 22-25 on page 4 (line 2) and page 7 (lines 5-8). The non-silica solid support of instant claims 27-29 is also disclosed on page 5 (lines 1-5) in the specification of '830: The vessel or container containing the solid support of claim 30 is disclosed on page 7 (lines 9-11) in the specification Of '830. Regarding the RNA Lysing Solution of instant claims 21 and 45, the specification of '830 discloses the use of the Lysing solution from Gentra Systems, Inc (page 5, lines 6-7). The nucleic acid lysing solution from Gentra Systems, Inc. is well known to be free of hazardous material such as strong chaotropic substance therefore the instant RNA Lysing solution of claims 21 and 45 (assignee Gentra Systems, Inc.) is inherently effective in order to form a lysate containing RNA from a biological material and free of any strong chaotropic substance. It would have been obvious to one having ordinary skill in this art, at the time the claimed invention was made to have optimized the amounts of the buffer and said RNA lysing solution to produce RNA from a biological material in combination with a solid support to accomplish a purified nucleic acid such

Art Unit: 1623

as RNA of the '830 co-pending application which have the same use and effect. One of ordinary skill in the art would be motivated to accomplish said method of purification since the beneficial effects of the active agents is individually taught in the prior art. The examiner notes the instant claims and said claims of the co-pending U.S. Application '830, of applicants do indeed substantially overlap therefore this obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: In the reply submitted February 21, 2007, Applicant argues that the '830 application was revived solely for the purpose of filing a continuation. However, as this application has not yet been abandoned, it is still considered to be pending, and the above rejection is deemed to be proper and maintained.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

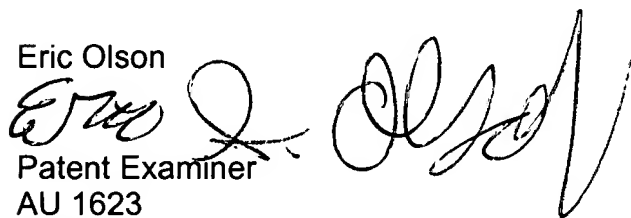
Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson

Patent Examiner
AU 1623
6/14/07



Anna Jiang

Supervisory Patent Examiner
AU 1623

